K081888

FEB – 6 2009

510k summary of safety and effectiveness

As required by section 807.92(c)

Submitter	SPINEART International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND
Contacts	Franck PENNESI Director of Industry & Quality Phone : +41 22 799 40 25 Fax : +41 22 799 40 26 Mail : fpennesi@spineart.ch Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr
Preparation date	Revised January 15, 2009
Trade Name	DYNAMIK Intervertebral body fusion device
Classification Name	Intervertebral body fusion device
Class	II
Product Code	MAX
CFR section	21 CFR 888.3080
Device panel	Orthopedic
Legally marketed predicate devices	LUMBAR I/F CAGE manufactured by DEPUY ACROMED (P960025), OPAL ORACLE SPACER (K072253) manufactured by SYNTHES SPINE and LUCENT Manufactured by SPINAL ELEMENTS INC (K071724)
Description	DYNAMIK range of products consists of lumbar Interbody cages available in various models to adapt to anatomical variations and surgical techniques. DYNAMIK cages are manufactured as single solid-machined piece made of PEEK conforming ASTM F2026. Markers made of titanium conforming ASTM F136 are used to visualize the position of the implant in the disc space. DYNAMIK Lumbar Interbody Devices are made of PEEK conforming ASTM F2026 with a titanium marker made of TA6V 4 ELI conforming to ISO 5832.3 and ASTM F 136 and are supplied sterile. DYNAMIK Lumbar Interbody Devices are supplied with a complete set of surgical instruments.

Intended Use	DYNAMIK Lumbar Interbody Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1, DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft. DYNAMIK Lumbar Interbody Device is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.
Performance data	DYNAMIK Lumbar Interbody Device conforms to Class II Special Controls Guidance Document: Intervertebral Body Fusion Device- Document issued on: June 12, 2007. Mechanical testing was conducted per ASTM F 2077-03 and ASTM F 2267-04
Substantial equivalence	DYNAMIK Lumbar Interbody Device is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2009

Spineart
% Mr. Franck Pennesi
International Center Cointrin
20, route de Pre-Bois
CP 1813
1215 Geneva 15
Switzerland

Re: K081888
Trade/Device Name: Dynamik Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: January 19, 2009
Received: January 21, 2009

Dear Mr. Pennesi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K081888

Device Name: DYNAMIK Lumbar Interbody Device

Indications for Use:

DYNAMIK Lumbar Interbody Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1, DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft. DYNAMIK Lumbar Interbody Device is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081888